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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,697	09/29/2005	Andreas Habich	268118US0PCT	4608

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EXAMINER	
PALENIK, JEFFREY T	
ART UNIT	**PAPER NUMBER**
1615	

NOTIFICATION DATE	DELIVERY MODE
05/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/528,697	HABICH ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12,13,15,16,19 and 21-25* is/are pending in the application.

4a) Of the above claim(s) *5-9,12,13,15,16,19 and 21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☒ Claim(s) *5-9,12,13,15,16,19 and 21-25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *22 Mar 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks

The Examiner thanks the Applicants for their timely reply filed on 22 January 2008, in the matter of 10/528,697.

Applicants' election **without traverse** of Group I, claims 1-9, 12, 13, 15, 16, 19 and 21-25, is acknowledged. Claims 10, 11, 14, 17, 18 and 20 hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 March 2008.

The remaining claims 1-9, 12, 13, 15, 16, 19 and 21-25 are presented and represent all claims under consideration.

Information Disclosure Statement

An Information Disclosure Statement (IDS) filed 22 March 2005 is acknowledged and has been reviewed.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves

modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claims 5-9, 12, 13, 15, 16, 19 and 21-25 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or, cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 and its dependent claims 2-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solid choline formulation, does not reasonably provide enablement for such a formulation with "reduced sensitivity to external factors". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The limitation for "reduced sensitivity to external factors" is extremely broad and encompasses a wide range of "external factors" which includes additional qualities which exist outside the context of the formulations discussed in the instant disclosure (specification, pg. 2, lines 25-30). As set forth in the prior art such as: *Remington: The Science and Practice of Pharmacy* (pg. 1458-1461), teaches external stressors such as temperature, pH and moisture, in addition to others such as oxidation, loss of optical activity due to racemization, excipient interaction and permeability. Given its broadest reasonable interpretation, the limitation "reduced sensitivity to external factors" with respect to the solid choline ascorbate formulation, is interpreted by the Examiner to define the formulation as further including a stabilizing additive compound. To this end, given that the instant invention is empirically drawn to a solid choline ascorbate formulation, the Examiner respectfully submits that one of ordinary skill in the art would be faced with an undue experimental burden in attempting to practice any particular embodiment of the invention commensurate in scope with the claims. That is, the instant invention is concerned with a broad range of potential embodiments which include any number

of additives which may contribute to the overall stabilization of the compound, whether included as part of the internal matrix or external (e.g. surface) coating, as disclosed in the instant specification, and an ordinary practitioner would need to undergo undue experimentation in order to formulate a given choline ascorbate composition without guidance from the prior art. As such, the disclosure of the instant specification is not sufficient to support the generic concept of "reduced sensitivity to external factors".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "reduced" in claim 1 is a relative term which renders the claim indefinite. The term "reduced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The parameter rendered indefinite by the use of the term "reduced" is the degree to which sensitivity to external stress factors is lowered. Otherwise stated, the effectivity of stabilizers within the compound to reduce sensitivity to external stressors is indefinite.

The recitation: "characterized in that a solution of this formulation has under standard conditions a Gardner color number (determined as specified in DIN-ISO 4630 or ASTM D 1544-80) of 4.5, and/or a Hazen color number (determined as specified in DIN-ISO 6271 or ASTM D 1045-68, ASTM D 263-49 or ASTM D 1209-69) of 800; and does not deliquesce on storage

under standard conditions in moist ambient air," in claim 1, renders the claim indefinite because the subject matter for which protection is sought, is not clearly defined (i.e. the solid or liquid composition?). Herein, and for the purposes of examination on the merits, the aforementioned "solution" limitation is interpreted by the Examiner as a future intended use of the solid choline ascorbate formulation. In light of the above "scope of enablement" rejection under *35 USC §112, first paragraph*, claim 1 is interpreted broadly and reasonably to claim a solid choline ascorbate formulation further including a stabilizing additive or compound.

The term "and/or" as recited in claim 4, renders said claim indefinite because it is not clear how the additive(s) are structurally related to choline ascorbate in the formulation. For the purposes of examination on the merits, the Examiner interprets the limitation to read on the "or" limitation such that the additive is mixed with the choline ascorbate or is present in the surface coating, in the inert matrix or in the porous carrier.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Völkel et al. (EP 1 234 815). European Patent (EP) 1 234 815, which is published in German, is also published in English as US Pre-Grant Publication No. 2002/0161039, as noted in Applicants' IDS.

The instant claims are drawn to a solid choline ascorbate composition additionally formulated with a stabilizer. Dependent claim 3, further limits the compositions of either claim 1 or 2 such that at least one other additive is included which further stabilizes the color of the composition. Dependent claim 4 further limits the composition of claim 3 such that the additional stabilizer is mixed with the choline ascorbate, the surface coating, the inert matrix, or the in the porous carrier.

Völkel et al. teach a solid choline ascorbate formulation in crystalline form (claim 1). Examples 4-6 teach multivitamin tablet formulations which include in their compositions vitamin derivatives and precursors which function to stabilize the overall choline ascorbate composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Völkel et al. (EP 1 234 815) in view of *Remington: The Science and Practice of Pharmacy*.

The instant claims are drawn to a stabilized, solid choline formulation as described above. Dependent claim 2 further limits said composition such that choline ascorbate is either embedded in an inert matrix or admixed within an inert surface-coating.

The teachings of Völkel with respect to claims 1, 3 and 4, are discussed above. Völkel also teaches that in addition to the multivitamin tablet compositions of Examples 4-6, that choline ascorbate may also be formulated using more inert encapsulation materials such as gelatin. Remington teaches on pg. 1397, that gelatin is partially "derived from the skin, white connective tissues and bones of animals" for the manufacture of capsules in which to dispense medicines. It is further taught that gelatin encapsulation material may be treated colorimetrically, chemically or physically in order to enhance the stability of the pharmaceutical formulation that it encases.

In view of the combined teachings of the prior art, one of ordinary skill in the pharmaceutical art would have been motivated to prepare a solid choline ascorbate composition containing a stabilizing agent further combining it with a proteinaceous animal-based material such as gelatin, with a reasonable expectation of successfully creating the inertly coated or admixed composition of the instant claims. Such would have been obvious in the absence of evidence to the contrary since gelatin, whether in the form of an encapsulation material or matrix additive, is a well known and established material useful for conveying long-term stability to pharmaceutical dosages, especially where storage in dry and light susceptible conditions are concerned (*Remington*, pg. 1397).

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615